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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,061	07/31/2003	Robert E. Richard	02-321	9972
27774	7590	12/19/2007	EXAMINER	
MAYER & WILLIAMS PC			SIMMONS, CHRIS E	
251 NORTH AVENUE WEST				
2ND FLOOR			ART UNIT	PAPER NUMBER
WESTFIELD, NJ 07090			1614	
			MAIL DATE	DELIVERY MODE
			12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,061	RICHARD ET AL.	
	Examiner	Art Unit	
	Chris E. Simmons	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 September 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 and 22-29 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 and 22-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the claims: Receipt of amendment on 09/17/2007 is acknowledged. Claim 1 is amended. Claim 21 is canceled. Claims 1-20 and 22-29 are pending.

RESPONSE TO ARGUMENTS

Applicant's remarks have been found persuasive. Applicant's amendments have overcome the rejections.

RESPONSE TO AMENDMENTS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9-20, 22-26, and 28-29 are rejected under 35 USC 103(a) as being unpatentable over **Pinchuk et al.** (US 2002/0107330) in view of **Schwarz** (US 2003/0236514).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are directed to an implantable or insertable medical device comprising a therapeutic agent and an acrylic graft copolymer which comprises hard units and rubbery units that controls the release of said agent.

'330 discloses an intravascular or intervascular medical device (e.g., a stent; ¶ 15) comprising a therapeutic agent-releasing biocompatible block polymer, said polymer is a copolymer that may be linear triblock (¶ 28) or branched (¶ 32), said copolymer comprising a therapeutic agent (e.g., heparin; ¶ 62), elastomeric blocks (e.g., polyolefins; ¶ 33 and claim 42) and thermoplastic blocks (e.g., vinyl aromatic blocks or methacrylate blocks (¶ 8 and claim 44), especially poly(methyl methacrylate) (¶ 8 claim 45)) (See abstract, ¶ 177-178.) The poly(methyl acrylate) in instant application is defined as a polyolefin due to alkene group in the methyl acrylate monomer.

'330 discloses the device further comprising a polymer or copolymer layer that may contain the biocompatible block copolymer (Claim 54) or may not contain the biocompatible block copolymer (Claim 55).

'330 also does not expressly disclose graft copolymers.

'514 discloses an implantable or insertable medical devices for controlled delivery of a therapeutic agent having a release layer comprising a maleic anhydride

polymer selected from (i) a maleic anhydride copolymer and (ii) a maleic anhydride graft polymer (Abstract).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create a biomedical stent made of grafted copolymers.

The suggestion/motivation for doing so would have been to increase the flexibility of a sterile and safe biomedical stent to facilitate conformity to the vessel or organ contour and its drug-releasing profile. Since release is modulated by changing the composition of the release layer ('514, ¶ 0017), the skilled artisan with a grafted copolymer has a more versatile stent (i.e., the additional side chains in addition to the main chain) to alter the composition of to manipulate its drug-releasing properties.

Therefore it would have been obvious to combine the references to obtain the claimed invention as specified in the instant claims.

Claim 8 is rejected under 35 USC 103(a) as being unpatentable over **Pinchuk et al.** (US 2002/0107330 A1) in combination with **Schwarz** (US 2003/0236514) taken in view of **Van Dijk et al.** (WO/2000/061203).

'330 in combination with '514 disclose as outlined above. However, they do not expressly disclose an elongation at break of at least 25% at ambient temperature.

'203 discloses a stent with elongation of at least 8% (Abstract).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create a biomedical stent having an elongation of break of at least 25%.

The suggestion/motivation for doing so would have been to increase the flexibility of a biomedical stent to facilitate conformity to the vessel or organ contour.

Claim 27 is rejected under 35 USC 103(a) as being unpatentable over **Pinchuk et al.** (US 2002/0107330 A1) in combination with **Schwarz** (US 2003/0236514) taken in view of and **Ding et al** (US Patent 5,837,313).

'330 in combination with '514 disclose as outlined above. However, they do not expressly disclose sterilizing using radiation.

'313 discloses sterilization of a stent prosthesis by exposing to radiation (Abstract).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create a radiation-exposed biomedical stent.

The suggestion/motivation for doing so would have been to make a sterile and safe biomedical stent for use in a subject.

Conclusion

No claims are allowed.

The following is pertinent art not relied upon for the current office action:

- WO 00/59968

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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December 1, 2007

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